

PATENTS
Attorney Docket No. 593/002 CIP 3 Cont.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

Applicants : Robert A. VanTassel et al.
Application No. : Not yet available
Confirmation No. : Not yet available
Filed : Herewith
For : FILTER APPARATUS FOR OSTIUM
OF LEFT ATRIAL APPENDAGE
Group Art Unit : Not yet available
Examiner : Not yet available

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ARGUMENTS FOR ALLOWABILITY OF APPLICATION

Sir:

Claims 1-15 of the application filed herewith correspond to claims 11-21, 24, 41, 51 and 52 of parent patent application No. 09/697,628, filed October 26, 2000. In this parent patent application, claims 11, 12, 18-21, 41, 51 and 52 were rejected under 35 U.S.C. § 102(e) as anticipated by Lesh et al. U.S. Patent 6,152,144 ("Lesh") and claim 20 was rejected under 35 U.S.C. § 103(a) as being obvious from Lesh. Applicants respectfully submit that these claims, cancelled from the parent application and now claims 1-15 of the current application filed herewith, are in condition for allowability for the following reasons.

According to claim 1, applicants' inventive implant device for filtering blood flow through the ostium of an atrial appendage includes a blood-permeable filter membrane that is placed across the ostium to intercept and filter blood flowing across the ostium. The filter confines thrombus to the atrial appendage, but allows thrombus-free blood to flow through.

The Examiner rejected this claim under 35 U.S.C. § 102(e) as anticipated by Lesh et al. U.S. Patent No. 6,152,144 ("Lesh"). The Examiner stated that Lesh discloses all the claimed subject matter. The Examiner in particular pointed to Figures 3a and 3b and column 2, lines 31-32. of Lesh

Applicants respectfully traverse. Applicants respectfully submit that the Examiner is mistaken, because Lesh does not disclose or suggest applicants' in-vivo blood filtration devices.

Applicants have previously noted in a related case (application No. 09/614,091, Atty. Docket No. 00593/002 CIP) that Lesh discloses devices and methods for occlusion but not for filtration. Lesh's devices occlude a body cavity to stop blood flow by "volumetric filling," "closing the opening ... with an occluding member," or "fixing [the opening] in a closed state" (see e.g., Lesh Abstract, and column 1, line 64-column 2, line 2). Applicants respectfully submit that teaching occlusive devices that close a body cavity to stop blood flow contradicts and teaches away from applicants' in-vivo filtration devices, which keep the body cavity open to allow blood flow.

Lesh does not mention or use the term blood flow, let alone describe filtered blood flow. Lesh defines embolic

material inclusively as "fluids, particulate in fluids such as blood clots, gas bubbles, solid tissue or the like" (column 4, lines 18-20). Lesh's occlusive devices and methods indiscriminately block passage of all materials whether they be fluids (blood) or suspended solids or gases (see e.g., column 2, lines 39-41, column 4, lines 16-18 of Lesh). There is no notion in Lesh of selectively filtering one or the other while keeping a blood flow across the atrial appendage ostium.

Applicants respectfully submit that read in context, Lesh's use of terms such as "pore size" and "mesh" in the description of occlusive devices does not make them filters or give them any filtration attributes.

First, the terms "barrier" and "mesh" in Lesh are alternate names referring to one and the same occluding material and not to two different materials or types of structures. For example, Lesh states: "The barrier 15 can be a thin mesh" (column 7, lines 47-49); "Typical examples of suitable materials for the barrier include a ... mesh" (column 2, lines 42-43); "Preferably, the barrier or mesh material is made from PTFE or ePTFE having a pore size of up to about 0.04 inches ..." (column 2, lines 43-45). Thus, both Lesh's barrier and mesh are the same. Lesh's "mesh" is not a filter membrane, but an occluder which "act[s] as a barrier" to prevent the passage of both fluids and particulate embolic material¹. (See e.g., column 2, lines 33-35, and lines 39-41 of Lesh).

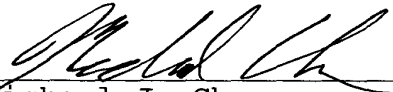
¹ As noted above, Lesh defines embolic material inclusively as "fluids, particulate in fluids such as blood clots, gas bubbles, solid tissue or the like" (col. 4, lines 18-20).

Second, the reference in Lesh to pore size relates to the inherent cellular structure of occlusive device construction materials PTFE and ePTFE, and not to flow-conductive pores or channels as in applicants' inventive filter devices. Applicants respectfully submit that the common and widely used family of bio-compatible Teflon® materials including PTFE and ePTFE have an inherent cellular structure arising from the cross-linking of fluoropolymers. This inherent cellular structure is a tortuous pore network, which often is quantified in common industry material data sheets by a figure of merit "pore size." However, the Teflon® materials are not per se fluid permeable despite their inherent cellular structures because their tortuous pore networks do not provide continuous or open fluid flow channels. Moreover, the Teflon® materials are hydrophobic. To function as aqueous or blood permeable filters, Teflon® material membranes have to be specially treated or provided with flow-conductive channels or pores that are different from the inherent tortuous pore network. Lesh does not disclose or suggest such special treatment or the addition of any flow-conductive channels.

The foregoing demonstrates that Lesh does not disclose the elements of applicants' claim 1 device. Accordingly, applicants respectfully submit that claim 1 and its dependent claims are patentable over Lesh.

For the reasons set forth above, this application
filed concurrently herewith is in condition for allowance.
Prompt allowance of this application is respectfully
requested.

Respectfully submitted,



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